

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
Office of Health and Safety F05
1600 Clifton Road NE

Form Approved
OMB No. 0920 0199

FAX (404)-639-3236

Atlanta, GA 30333

(404)-639-3883

APPLICATION FOR PERMIT TO IMPORT OR TRANSPORT
AGENTS OR VECTORS OF HUMAN DISEASE

Let us know if you have already faxed your application

INSTRUCTIONS: Complete and submit original signed copy to:

Centers for Disease Control, Attn: Office of Health and Safety, F05, Atlanta, Georgia 30333

USE ADDITIONAL SHEETS IF NECESSARY

1. PERSON REQUESTING PERMIT in USA	NAME, ORGANIZATION, ADDRESS, PHONE:		
2. SOURCE OF MATERIAL	NAME OF SENDER, ORGANIZATION, ADDRESS:		
3. DESCRIPTION OF MATERIAL	NAME, ORIGINAL GEOGRAPHIC AND HOST SOURCE AND CULTURE HISTORY OF AGENT OR VECTOR:		
4. TYPE OF PERMIT REQUESTED	IMPORTATION INTO U.S.: <input type="checkbox"/> Single <input type="checkbox"/> Multiple No. of shipments expected to be made within the next 12 months periods		TRANSFER WITHIN THE U.S.: <input type="checkbox"/> Single <input type="checkbox"/> Multiple
5. SHIPMENT INFORMATION	METHOD OF TRANSPORT: <input type="checkbox"/> Mail <input type="checkbox"/> Air Freight <input type="checkbox"/> Hand Carry <input type="checkbox"/> Other _____	U.S. PORT(S) of ARRIVAL:	
6. QUANTITY OF MATERIAL TO BE IMPORTED	INDICATE VOLUME AND TYPE OF INDIVIDUAL CONTAINERS: (Reference 42 CFR 72)		
7. PROPOSED USE OF MATERIAL	INDICATE OBJECTIVES AND PROPOSED PLAN OF WORK; COMPLETION DATE; FINAL DISPOSITION OF MATERIAL(S):		
8. ISOLATION AND CONTAINMENT FACILITIES	DESCRIBE AVAILABLE FACILITIES:		
9. TECHNICAL PERSONNEL	QUALIFICATIONS AND EXPERIENCE OF TECHNICAL PERSONNEL:		

I certify that the material(s) will be used in accordance with all Restrictions and Precautions as may be specified in the Permit(s).

10. APPLICANT	SIGNATURE:	DEGREE(S)	11. TITLE:	12. DATE SIGNED:
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IMPORTATION PERMIT FEDERAL REGULATION

Federal Register/Vol. 50 No. 8/ Friday, January 11, 1985
Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN
 SERVICES
 Public Health Service
 42 CFR Part 71
 Foreign Quarantine

Agency: Centers for Disease
 Control,
 Public Health Service, HHS
 Action: Final Rule

SUMMARY: This rule amends the regulations in 42 CFR Part 71 necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. In 1987, the public Health Service was reorganized and the Quarantine Program was transferred to the Centers for Disease Control (CDC). Since the transfer, the Quarantine Program has been modernized and streamlined. The regulations have been updated to reflect current concepts of disease surveillance, investigation, and control.
EFFECTIVE DATE: February 11, 1985.

71.54 Etiological agents, hosts, and vectors

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

71.55 Dead bodies

The remains of a person who died of a communicable disease listed in 71.32 may not be brought into a U.S. port unless the body is (a) properly embalmed and placed in a hermetically sealed casket, (b) cremated or (c) accompanied by a permit issued by the Director.

CENTERS FOR DISEASE CONTROL AND PREVENTION
OFFICE OF HEALTH AND SAFETY M/S (F-05)
BIOSAFETY BRANCH
1600 Clifton Road
Atlanta, Georgia 30333

Phone (404) 639-3883
FAX (404) 639-3236

Permit Officers:

Richard C. Knudsen, Ph.D.
Henry M. Mathews, Ph.D.

GENERAL INFORMATION ON IMPORTATION PERMITS FOR ETIOLOGIC AGENTS

INTRODUCTION

Etiologic agents are those microorganisms that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans, and parasites. These disease causing microorganisms may also be referred to as infectious agents or infectious substances and the materials, such as body fluids and tissues that contain them, are referred to as infectious materials. Organisms such as mosquitoes that may transmit infectious diseases to other humans are called vectors.

Etiologic agents and the vectors and other materials that may contain them, are recognized by the federal government and state governments as hazardous materials. Infectious materials are regularly transported from one location to another by common land and air carriers. Containers of infectious materials must be carefully packaged to prevent breakage or leakage to avoid exposure of the package handlers, transporters, and the general public to the package contents. The package must be labeled with the universal biohazard sign to warn package handlers of the hazardous contents. When a package of infectious material is being imported into the United States it must be accompanied by an importation permit.

IMPORTATION PERMITS

Many etiologic agents, infectious materials or vectors containing infectious agents are imported from foreign locations into the United States for domestic use and study. Packages containing etiologic agents originating in these foreign locations must have an importation permit issued by the United States Public Health Service. Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labelling, will expedite

clearance of the package of infectious materials through the United States Public Health Service Division of Quarantine and release by U.S. Customs.

The importer bears responsibility for assuring that the foreign shipping personnel pack and label the infectious materials according to USPHS regulations. Transfers of previously imported material within the U.S. also require a permit for the same reason.

Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date, are also issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U.S. Customs Service and U.S. Division of Quarantine Personnel of the package contents.

FEDERAL REGULATION

The importation of etiologic agents is governed by the following federal regulation:

USPHS 42 CFR - Part 71 Foreign Quarantine. Part 71.54
Etiologic agents, hosts, and vectors.

(a) A person may not import into the United States, nor distribute after importation, any etiologic agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of U.S. Customs Service of a permit issued by the Director (Centers for Disease Control and Prevention).

ITEMS REQUIRING PERMITS

Etiologic agents. It is impractical to list all of the several hundred species of etiologic agents. In general, an import permit is needed for any infectious agent known to cause disease in man. This includes, but is not limited to, bacteria, viruses, rickettsia, parasites, yeasts and molds. In some instances, agents which are suspected of causing human disease also require a permit.

Vectors

Animals Any animal known or suspected of being infected with any disease transmissible to man.

Importation of turtles of less than 4 inches in shell length and all non-human primates requires an importation permit issued by the Division of Quarantine. Telephone (404) 639-8100 for further information.

Biological materials Unsterilized specimens of human and animal tissue (including blood), body discharges, fluids, excretions or

similar material, when known or suspected of being infected with disease transmissible to man require a permit under these provision in order to be imported.

Insects Any living insect, or other living arthropod, known or suspected of being infected with any disease transmissible to man. Also, if alive, any fleas, flies, lice, mites, mosquitoes, or ticks, even if uninfected. This includes eggs, larvae, pupae, and nymphs as well as adult forms.

Snails Any snails capable of transmitting schistosomiasis. No mollusks are to be admitted without a permit from either Centers for Disease Control or the Department of Agriculture. Any shipment of mollusks with a permit from either agency will be cleared immediately.

Bats All live bats will require a permit from the U.S. Department of Interior, Fish and Wildlife Services or CDC.

LETTERS OF AUTHORIZATION

After review of an "Application to Import an Etiological Agent" the issuing officer may issue a "Letter of Authorization" rather than an importation permit. The Letter of Authorization is issued for materials that are judged to be non-infectious, but which might be construed to be infectious by U.S. Customs inspection personnel.

Letters of Authorization may be issued for items such as formalin fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine, cerebrospinal fluid, and other tissues or materials of human origin when there is no evidence or indication that such materials contain an infectious agent.

Letters of Authorization are in effect for two years, and do not require a shipping label to be issued by this office.

PACKAGING REQUIREMENTS

Infectious materials imported into this country must be packaged to withstand breakage and leakage of contents, and labelled, as specified in the following federal regulations:

USPHS 42 CFR Part 72 - Interstate Shipment of Etiologic Agents.
DOT 49 CFR PART 173 - Transportation of Etiologic Agents
For international shipments, the International Air Transport Association (IATA) Dangerous Goods Regulations should be consulted.

OTHER PERMITS

United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) permits are required for infectious agents of livestock and biological materials containing animal, particularly livestock material.

Tissue (cell) culture techniques customarily use bovine material as a stimulant for cell growth. Tissue culture materials, and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origin are, therefore, controlled by the USDA due to the potential risk of introduction of exotic animal diseases into the

U.S. Further information may be obtained by calling the USDA/APHIS at (301) 734-7885.

United States Department of Interior (USDI) permits are required for certain live animals and all live bats. Call (202) 358-2095 for further information.

EXPORTS OF INFECTIOUS MATERIALS

The export of infectious material may require a license from the Department of Commerce. Call (202)482-4811 for further information.

COMPLETING THE "APPLICATION TO IMPORT OR TRANSPORT AGENTS OR VECTORS OF HUMAN DISEASE"

INTRODUCTION

Importation permits and Letters of Authorization are issued by the Biosafety Branch, Office of Health and Safety, Centers for Disease Control and Prevention after review of a completed application form. Application forms may be obtained by calling (404) 639-3883. Completed application forms may be returned to the Biosafety Branch by mail or FAXED: 404-639-3236.

Application for the importation permit should be made 10 working days in advance of the shipment date to allow time for processing, issuance and delivery of the permit and shipping labels to the permittee.

Application forms may be handwritten or typed. All forms must be readable. Unreadable forms or incomplete information will delay permit issuance. If more space is needed for a block, use additional sheet(s), noting the block number. Please provide telephone number and FAX number of the permittee in case questions arise.

BLOCK 1. (PERMITTEE) The person requesting the permit (applicant) should be (1) knowledgeable and skilled in the handling of the infectious agent or biological material, (2) be directly responsible for work with the infectious material, and (3) should be located at the address within the U.S. where work with the infectious material will be performed. Regulatory affairs officers or other general administrative personnel are generally not acceptable as permittees.

Enter your complete name, telephone, FAX number and address. Failure to include the telephone and FAX numbers where you can be reached during the day will result in prolonged delays if we have to contact you.

The name appearing in this block, and in Block 10 should be the same. One or more names may be used here. For each name used in Block 1, there must be a corresponding signature in Block 10.

BLOCK 2. Enter complete name and address of the sender. Multiple sources may be listed on an attached sheet as needed. Indicate which source is supplying which infectious material. Include telephone and FAX numbers if possible.

BLOCK 3. Complete as indicated. Include the common name, genus, species and biosafety level of the agent if known. Describe any animal products in the material. This block determines whether a permit or a Letter of Authorization will be issued. Importation permits will be issued for infectious agents or materials known, or suspected, to contain infectious materials. Letters of Authorization will be issued for biological materials that are not infectious or hazardous. Please answer these questions here: (1) is the material infectious? (2) is the material hazardous? (3) does it contain any animal products? i.e. bovine albumin; and (4) the biosafety level of the organism, if known. We will issue both infectious agents Importation Permits and Letters of Authorizations to the same person if needed and requested.

BLOCK 4. Importation into the U.S. refers to the package as passing through the port of entry to the applicant's address. (EXPORTING, REFER TO DEPARTMENT OF COMMERCE: (202)482-5808) Moving imported material from one air carrier to another at the Port of Entry on the way to its domestic destination is not considered a transfer for the purposes of this permit. A transfer within the U.S. refers to shipping from one address within the U.S. to another address within the U.S.

Permits for single importations are valid for six months.
Permits for multiple importations are valid for one year.
Letters of Authorizarion are valid for two years.

For multiple shipments, enter the number of shipments you expect to receive in the next 12 months and number of transfers you expect to make in the next 12 months. One importation label is issued per shipment.

BLOCK 5. Complete as indicated.

BLOCK 6. Complete as indicated.

BLOCK 7. In describing objectives, please state the intended use(s): infectious disease research or diagnosis, genetic studies or analysis, chemical or biochemical analysis, enzyme assays, population profiles, kit development, etc.

BLOCK 8. Explain the biosafety level of the laboratory where the work will occur and any other information pertinent to available facilities.

BLOCK 9. Complete as indicated.

BLOCK 10. Remember to sign the form before it is FAXED or mailed. The signature (block 10) should be SIGNED by the person(s) requesting the permit. (Block 1). Type or print the name(s) in the "applicant" section of the person(s) who signs in the "signature" section.